



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m2443n

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

RECEIVED

March 9, 1999

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 21

Claire T. Hovland  
Chairman of the Board and CEO  
Urometrics, Inc.  
445 Etna Street, Suite 56  
St. Paul, Minnesota 55106

Dear Mr. Hovland:

We are writing to you because on January 26 through February 5, 1999, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the penile tumescence monitors that are manufactured at your facility in St. Paul, Minnesota.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. They are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found that the devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of medical devices are not in conformance with the Good Manufacturing Practices (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by Title 21, Code of Federal Regulations (CFR), Part 820.

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Our inspection found your products are in violation of the law because of:

1. Failure to establish and maintain procedures for the identification, documentation, validation, or appropriate verification, review and approval of design changes before their implementation as required by 21 CFR 820.30(i) in that there is no data to show that the NEVA program version 2.2.1 (revised 1/20/99) was validated or verified. The NEVA Program Released Software Description for version 2.2.1 references testing that was performed on earlier versions of the software rather than the final version.
2. Failure to establish and maintain procedures for implementing corrective and preventive action (21 CFR 820.100) in that the firm lacks procedures to control the design process for the NEVA.
3. Failure to establish and maintain procedures for acceptance activities [21 CFR 820.80(c)] in that there is no documentation that test results used in the acceptance of in-process product have been verified against the approved specifications.
4. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure with verification of validation according to Section 820.75 where appropriate and approval in accordance with Section 820.40 [21 CFR 820.70(b)].

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

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The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As CEO, the most responsible individual at Urometrics, Inc., it is ultimately your responsibility to ensure that devices manufactured at your facility in St. Paul, Minnesota, are in compliance with each requirement of the Act and regulations.

We have received your letter dated February 11, 1999, responding to the form FDA-483 issued to you on February 5, 1999. Your response adequately addresses the concerns referenced in the form FDA-483. However, it lacks specific documentation, including procedures, forms, and reports that would allow us to assess the effectiveness of your proposed corrective actions.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Quality System Requirements for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

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If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 2/5/99